

Remarks

Amendments to the Claims

Claims 1-11, 14, 16, and 18 were pending in this application. Claims 16 and 18 are cancelled herein. Applicants expressly reserve the right to pursue protection of any or all of subject matter cancelled by this Amendment in a subsequent application.

Claims 1, 3, 6, 8, and 14 are amended herein, and new Claims 28-31 are added. Support for the term “95%” in Claim 1 can be found for instance on page 13, line 37, of the specification. Support for the term “95%” in Claims 6 and 14 can be found for instance on page 14, line 14, of the specification. Support for the term “that encodes a protein having desaturase activity” in Claim 6 can be found for instance on page 6, lines 21-22 of the specification. Support for the term “high-stringency” in Claim 8 can be found for instance on page 11, line 33, as well as on page 12, of the specification. Claims 1 and 3 are amended to correct obvious clerical errors.

Support for new Claim 28 can be found for instance in original Claim 8, as well as on page 11, line 33 of the specification. In addition, support for new Claims 29-31 can be found in original Claims 9-11, which appear on pages 39-40, as well as throughout the specification.

No new matter is introduced by these amendments. After entry of this amendment, **Claims 1-11, 14, and 28-31 are pending in the application.**

Claim Rejection under 35 U.S.C. §112, Second Paragraph

Claim 3 is rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action points out that Claim 3 is drawn to an isolated nucleic acid comprising a sequence as shown in SEQ ID NO: 2, but that SEQ ID NO: 2 is an amino acid sequence.

Claim 3 has been amended herewith to recite SEQ ID NO: 3, the nucleic acid sequence that encodes the amino acid sequence shown in SEQ ID NO: 4 (see, *e.g.*, page 6, lines 25-28 of the specification). Applicants believe that Claim 3 as amended particularly points out and

distinctly claims the subject matter which Applicants regard as the invention, and respectfully request that this rejection be withdrawn.

Claim Rejection under 35 U.S.C. §112, First Paragraph

Claims 1, 9, and 18 are rejected under 35 U.S.C. § 112, first paragraph because the specification allegedly does not reasonably provide enablement for a desaturase that is:

at least 60% identical to SEQ ID NO: 4 (referring to Claim 1(c));
encoded by a nucleotide sequence that hybridizes under low stringency hybridization conditions to SEQ ID NO: 3 or fragments thereof (referring to Claim 9); or
encoded by a nucleotide sequence that hybridizes to 10 consecutive nucleotides of SEQ ID NO: 3 under any hybridization condition (referring to Claim 18). Applicants traverse this rejection.

Claim 1(c), has been amended herewith to change “at least 60%” to “at least 95%” sequence identity. Applicants submit that the specification is enabling for a desaturase as claimed in Claim 1. Even if some experimentation were required to practice the invention as claimed (and Applicants do not admit that is the case), Applicants submit that any such experimentations would not be undue or unreasonable, which is the applicable standard (M.P.E.P. § 2164.01). Even complex experimentation, involving an extended period of time and expense, is not necessarily undue if the experimentation is routine and the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed (M.P.E.P §§ 2164.01, 2164.06).

In the present case, the claimed amino acid sequences (those having at least 95% identity to the specified sequences, and having desaturase activity) may be readily identified and isolated using the teachings of the specification and routine techniques well known in the art. The specification provide SEQ ID NO: 4, and describes how to generate and test sequences 95% identical thereto. For instance, the specification teaches algorithms and methods for sequence identity comparison (see pages 9 and 10), amino acid substitutions and cloning (see pages 21-23), protein expression (see pages 23 and 24), and enzymatic assay (see Example 9). The specification provides sufficient information regarding these methods to allow a person of

ordinary skill in the art to make and use the invention, which is the criterion for 35 U.S.C. § 112, first paragraph. Applicants therefore respectfully request that this rejection be withdrawn.

Claim 9 is directed to a desaturase encoded by the nucleic acid molecule of Claim 8. Claim 8 has been amended herewith to require hybridization under high-stringency conditions, examples of which conditions are provide in the specification (see page 12). Applicants submit that the specification is enabling for a desaturase encoded by the nucleic acid molecule of Claim 8, as amended. For example, the specification teaches methods for forming a hybrid between the primer and target nucleic acid molecule under high-stringency conditions (pages 11 and 12), cloning of nucleic acid molecules (pages 21-23), protein expression (pages 23 and 24), and enzymatic assay (Example 9). The specification provides sufficient information regarding these methods to allow an ordinary skilled artisan to make the claimed invention without undue experimentation, which is the criterion for 35 U.S.C. § 112, first paragraph, as discussed above. Applicants therefore respectfully request that this rejection be withdrawn.

Claim 18 has been cancelled by this Amendment, therefore rendering moot the 35 U.S.C. § 112, first paragraph rejection. The cancellation is not an admission that the rejection was correct, and Applicants reserve the right to pursue the subject matter of Claim 18 in a subsequent application.

Claims 2-8, 10-11, 14, and 16 are rejected under 35 U.S.C. § 112, first paragraph because the specification allegedly does not reasonably provide enablement for a DNA:

encoding a desaturase that has 60% sequence identity to SEQ ID NO: 4 (referring to Claims 2-7);

that is 60% identical to SEQ ID NO: 1 (referring to Claim 6);

encoding a desaturase which hybridizes under low stringency hybridization conditions to SEQ ID NO: 3 or fragments thereof (referring to Claims 8, 10, and 11); or

encoding a desaturase which hybridizes to 10 consecutive nucleotides of SEQ ID NO: 3 under any hybridization condition (referring to Claim 16). Applicants traverse this rejection.

Claim 2 is drawn to an isolated nucleic acid molecule encoding a protein according to Claim 1. As discussed above, Claim 1 has been amended herewith to change “at least 60%” to

“at least 95%” sequence identity. Applicants submit that the specification is enabling for the claimed nucleic acid molecules, for the statutory reasons argued above. For example, the specification teaches algorithms and methods for sequence identity comparison (pages 9 and 10); amino acid substitution, polymerase chain reaction amplification and cloning (pages 21-23); protein expression (pages 23 and 24); and enzymatic assays (Examples 9 and 12). The specification provides sufficient information regarding these methods to allow a skilled person to make the invention without undue experimentation, which is the criterion for the 35 U.S.C. § 112, first paragraph requirement. Applicants therefore respectfully request that this rejection be withdrawn.

Claims 3-7 are rejected on the same ground as Claim 2. By dependency, the amendment to Claim 1 is now included in Claims 3-7. For the reasons set forth above, Applicants therefore request that the rejection of Claims 3-7 on this ground be withdrawn.

Claim 6 is separately rejected in reference to sequence identity for SEQ ID NO: 1. As discussed above for Claim 1 and 2, Claim 6 has been amended to change “60%” sequence identity to “at least 95%” sequence identity (to the nucleic acid molecule as shown in SEQ ID NO: 1). For the same reasons as discussed for SEQ ID NO: 4 and Claims 1 and 2, Applications believe the amendment to Claim 6 is sufficient to overcome this rejection and ask that the rejection be withdrawn.

Claim 8 has been amended herewith to require hybridization under high-stringency conditions. Applicants submit that the specification is enabling for the nucleic acid molecule of Claim 8 as amended, for the reasons stated above in reference to Claim 9. In particular, the specification teaches methods for forming a hybrid between the primer and target nucleic acid molecule under high-stringency conditions (pages 11 and 12), cloning of nucleic acid molecule (pages 21-23), protein expression (pages 23 and 24), and enzymatic assay (Example 9). The specification provides sufficient information regarding these methods to allow a person of ordinary skill to make and use the invention, which is the criterion for the 35 U.S.C. § 112, first paragraph requirement. Applicants therefore respectfully request that this rejection be withdrawn.

Claims 10 and 11 are rejected on the same ground as Claim 8. By dependency, the amendment to Claim 8 is now included in the text of these claims. For the reasons set forth above, Applicants respectfully request that rejections of Claims 10 and 11 on this ground be withdrawn.

Claim 14 has been amended herewith to require at least 95% sequence identity (rather than 60% sequence identity).. Although the Office Action does not provide specific reason(s) for rejecting Claim 14, Applicants submit that the specification is enabling for the nucleic acid molecule as now claimed, for the reasons discussed above in regards to Claim . For example, the specification teaches algorithms and methods for sequence identity comparison (pages 9 and 10), polymerase chain reaction amplification and cloning (pages 21-23), protein expression (pages 23 and 24), and enzymatic assay (Example 9). The specification provides sufficient information regarding these methods to allow a person of ordinary skill to make and use the invention, which is the criterion for the 35 U.S.C. § 112, first paragraph requirement. Applicants therefore respectfully request that this rejection be withdrawn.

Claim 16 has been cancelled by this Amendment, therefore rendering moot the 35 U.S.C. § 112, first paragraph rejection. The cancellation is not an admission that the rejection was correct, and Applicants reserve the right to pursue the subject matter of Claim 16 in a subsequent application.

Claim 6 is rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants traverse the rejection.

The written description requirement of 35 U.S.C. § 112, first paragraph, calls for a showing that the applicant was in possession of the claimed invention by describing “complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” (M.P.E.P. § 2163). Furthermore, the Written Description Guidelines (Federal Register Vol. 66, No. 4, Friday January 5, 2001 “Notices”, pages 1099-

1111), citing *Regents of the University of California v. Eli Lilly and Co.*, 43 USPQ 1398 (Fed. Cir. 1997), recognize that describing the DNA sequence of a claimed DNA is only one method of satisfying the written description requirement and state that “there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.”

Claim 6 has been amended herewith to specify that the nucleic acid molecule has at least 95% sequence identity to SEQ ID NO: 1, and encodes a protein having desaturase activity. The specification provides the nucleotide sequence of an exemplary delta 5 desaturase from *Caenorhabditis elegans* (SEQ ID NO: 1), teaches that the exemplary nucleotide encodes a protein having desaturase activity (Example 12), and discloses algorithms and methods for sequence identity comparison (pages 9 and 10). The claim as amended recites structural and functional features by reference to a specific molecule with known sequence (SEQ ID NO: 1) and testable function (encoding protein having a desaturase activity), and a defined low level of sequence variation (95% identical to SEQ ID NO: 1). The claimed genus of sequences is not unreasonably broad.

The specification provides structural and functional description of the claimed nucleic acid molecule in Claim 6, and thus satisfies the written description requirement. Applicants therefore respectfully request that this rejection be withdrawn.

Conclusions

Based on the foregoing amendments and arguments, the claims are in condition for allowance and Applicants respectfully request that a timely Notice of Allowance be issued in this case. If for any reason Examiner Rao believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at (503) 226-7391.

Respectfully submitted,

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